TITLE OF INVENTION

Ultras nic Sens r Garment f r Breast Tum r D t cti n

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] Not Applicable

STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT

[0002] Not Applicable

BACKGROUND OF THE INVENTION

1. Field of Invention

[0003] This invention pertains to a system for detecting cancerous tumors within a human breast. More particularly, this invention pertains to a system for ultrasonically monitoring and logging tissue development within human breasts in order to detect localized tissue abnormalities.

2. Description of the Related Art

[0004] Breast cancer claims the lives of tens of thousands of women every year. Many of these victims could have survived if the cancer had been detected and treated in its primary stages. The most effective method of detecting this disease in its primary stages is regular periodic breast examinations. Currently, the three most common methods of breast examination are monthly self-examinations, annual mammograms, and clinical examinations. Monthly self-examinations require a woman to detect by touch and identify an abnormal "lump" within her breast using her hands. This method of palpation is limited in that by the time a "lump" is large enough to be felt by the woman, abnormal tissue development has progressed past its primary stages. Additionally, certain populations of women have naturally "lumpy" breast tissue. This condition introduces an additional degree of difficulty for a woman attempting to detect an abnormal "lump".

[0005] Annual mammograms are currently the standard in breast examinations. These examinations include compressing a breast and passing X-rays through the breast in order to produce an image of the entire organ. Mammograms are limited in that they are inconvenient, somewhat painful, use radiation, and produce only a "snapshot" of the organ. Further, a shortage in radiologists has presented additional limitations to this method. However, the most significant limitation associated with this method of breast cancer detection is the significant percentage of cancerous tumors left undetected.

[0006] Clinical examinations, like mammograms, are important in detecting breast cancer. However, also like mammograms, clinical examinations are inconvenient and provide only a "snapshot" of a breast.

[0007] Ultrasonic imaging is a useful tool for detecting abnormal tissue development within a female breast. Recent studies have revealed that abnormal tissue development missed by mammograms is detectable with ultrasonic technology. However, ultrasonic imaging is highly dependent on operator technique and is a very tedious procedure that can possibly result in an incomplete scan. Further, clinical ultrasounds require the application of messy ultrasound gels for eliminating an interfering layer of air between the sensor and the patient.

[0008] The apparatus of United States Patent Number 6,117,080 issued to Schwartz is a system utilizing ultrasonic energy for detecting breast cancer. More specifically, the apparatus transmits ultrasonic energy and reads the corresponding echoes produced by a patient's tissue to determine the presence of a tumor. This system is limited in that it requires the sliding of a scanning head across the patient's breast by a trained ultrasonographer, which consequently requires a clinical visit. Further, a waterbag device is required as a coupling agent for the scanning head and the patient's breast in order for the apparatus to reveal a clear and accurate image.

[0009] The apparatus of United States Patent Number 5,997,477 issued to Sehgal also utilizes ultrasonic energy for detecting breast tumors. This apparatus employs a driving signal transmitter that directs a first signal toward a calcification that causes the calcification to resonate. The apparatus further employs an

imaging signal transmitter that directs a second signal toward the calcification. A receiver then detects a resonance echo signal produced by the first signal and second signal in order to determine characteristics of the calcification under consideration. This apparatus is limited in that it requires a plurality of types of transmitters along with corresponding receivers in order to detect tumors within a human breast.

[0010] Finally, the apparatus of United States Patent Number 5,678,565 issued to Sarvazyan is a system for utilizing ultrasonic energy combined with a pressure sensing device for detecting tumors within a human breast. A scanning head containing a pressure sensor and ultrasonic scanning capabilities is slid across a breast so that the pressure sensor detects tissue elasticity changes while the ultrasonic component processes backscattered ultrasonic signals. The combination of readings reveals the presence of a cancerous tumor. However, this apparatus is limited in that it requires both pressure and ultrasound readings in order to detect a cancerous tumor. Further, the reliable use of this apparatus requires a trained ultrasonographer, which requires a clinical visit.

BRIEF SUMMARY OF THE INVENTION

[0011] In accordance with the present invention there is provided a cancer detection system that utilizes ultrasonic technology for gaining information regarding the tissue development of a female breast. The cancer detection system includes a plurality of ultrasonic sensors that are held in position around a patient's breasts by a garment. The sensors, in one embodiment, are transceivers and, in another embodiment, are individual transmitters and receivers. A transmitting sensor emits an ultrasonic pulse that is received by the receiving sensors that have a direct line-of-flight to the transmitting sensor. The time-of-flight of the received signal indicates the distance between the transmitting sensor and the receiving sensor. Density changes in the breast tissue, which may be indicative of a tumor or be due to a normal feature of the breast, affect the amplitude of the received signal. In another embodiment, the cancer detection system records reflected signals in addition to the direct signals, thereby increasing the resolution and precision of the cancer detection system.

[0012] A multitude of line-of-flight data collected from all sensors with all sensors sequentially serving as a transmitting sensor is processed to produce a pair of virtual breasts. The virtual breasts are collected over a period of time and are compared one to another to determine if any changes are occurring in the breast, other than natural changes resulting from normal physiological changes of the breast tissue.

[0013] In one embodiment, the cancer detection system is used within the home and communicates with the doctor of the patient by way of the Internet. In another embodiment, the cancer detection system is used in a clinical setting. The cancer detection system stores all information from the periodic examinations of a particular patient and builds a chronological profile of her breast tissue development. If a localized tissue abnormality becomes apparent, proper action is taken to determine if the abnormality is the early development of a cancerous tumor. Because the cancer detection system detects abnormal tissue development in its primary stages, if a cancerous tumor is found, an immediate treatment will greatly increase the probability of a successful treatment.

[0014] The cancer detection system, in one embodiment, includes a local processing device that loads a breast examination program from a remote processing device by way of the Internet. The local processing device utilizes a sensor garment, comprised of a number of ultrasonic transceivers, to produce an ultrasonic image of the tissue of a breast. The ultrasonic transceivers are positioned about the sensor garment such that they surround an entire breast. Once positioned around a breast, the ultrasonic transceivers transmit and receive a series of signals that are analyzed in the amplitude and time domain in order to detect a localized tissue abnormality and to isolate the location of the potentially cancerous abnormality within the breast. The positioning and operation of the ultrasonic transceivers allow a woman to obtain a breast examination without the assistance of a trained clinician. The ultrasonic images acquired from an examination are stored in the local processing device until they are loaded to the remote processing device. From the remote processing device, a doctor examines the results of the recent examination with respect to the results of previous examinations. These comparisons reveal, if present, the development of a localized

tissue abnormality. The early detection of these tissue abnormalities allows doctors to diagnose and treat the abnormalities in order to prevent the development of a fatal cancerous tumor.

BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWINGS

[0015] The above-mentioned features of the invention will become more clearly understood from the following detailed description of the invention read together with the drawings in which:

Figure 1 is a pictorial block diagram of one embodiment of a cancer detection system;

Figure 2 is block diagram illustrating one embodiment of the electrical components of the cancer detection system of Figure 1;

Figure 3 is a flow diagram illustrating the operation of one embodiment of a local processing device;

Figure 4 is a perspective view of one embodiment of an ultrasonic device;

Figure 5 is a side elevation view of the ultrasonic device of Figure 4 in section;

Figure 6 is a flow diagram illustrating the transmission and reception of a single ultrasonic signal;

Figure 7 is a sectional view of a breast accommodating cup illustrating the detection of a localized tissue abnormality by way of direct line-of-flight signal components;

Figure 7a is a pictorial view of an ultrasonic beam between a transmitting sensor and a receiving sensor with a large obstruction partially in the beam;

Figure 7b is a pictorial view of an ultrasonic beam between a transmitting sensor and a receiving sensor with a small obstruction;

Figure 8 is a timing diagram illustrating the signal analysis utilized in determining the presence and location of a localized tissue abnormality;

Figure 9 is a sectional view of a breast accommodating cup illustrating the detection of a localized tissue abnormality by way of reflected signal components;

Figure 10 is a sectional view of a breast accommodating cup further illustrating the detection of a localized tissue abnormality by way of direct line-of-flight signal components; and

Figure 11 is a sectional view of a breast accommodating cup illustrating the signal coverage provided by the present invention.

DETAILED DESCRIPTION OF THE INVENTION

[0016] One embodiment of a cancer detection system constructed in accordance with the various features of the present invention is illustrated generally at **10** in Figure 1. The cancer detection system **10** utilizes ultrasonic technology for gaining information regarding the tissue development of a female breast. The illustrated embodiment of the cancer detection system **10** includes a portion that is used within the home and that communicates with a remote portion by way of the Internet. The cancer detection system **10** stores all information from the periodic examinations of a particular patient and builds a chronological profile of her breast tissue development. If a localized tissue abnormality becomes apparent, proper action is taken to determine if the abnormality is the early development of a cancerous tumor. Because the cancer detection system **10** detects abnormal tissue development in its primary stages, if a cancerous tumor is found, an immediate treatment will greatly increase the probability of a successful treatment.

[0017] Figure 1 illustrates a pictorial block diagram of one embodiment of a cancer detection system **10** that includes a sensor garment **12**, a local processing device **20**, and a remote processing device **22**. Another embodiment includes a sensor garment **12** and a processor, which performs the functions of the local processing device **20** and the remote processing device **22**. This embodiment is

suitable for a clinical environment or where the processing of the data is to be performed by the data acquisition processor, which in the first embodiment is the local processor **20**. Hereinafter, the embodiment illustrated in Figure 1 is discussed, although the invention is not limited to such an embodiment.

[0018] The sensor garment **12**, in the illustrated embodiment, is a garment that resembles a sports bra. The sensor garment **12** includes a first cup **14** and second cup **16** for accommodating breasts during an examination. The first cup **14** and the second cup **16** each include a number of sensors **18**. In the illustrated embodiment, the sensors **18** are transceivers that transmit and receive ultrasonic energy. In another embodiment, the sensors **18** include both individual transmitters and receivers. The sensors **18** are mounted within the sensor garment **12** such that they completely surround a breast and provide signal coverage for the entire organ. The ultrasonic signals transmitted and received by the sensors, or ultrasonic devices, **18** produce the breast tissue information necessary to detect a localized tissue abnormality. One of the ultrasonic devices **18** transmits a pulse signal, which is received by the other ultrasonic devices **18** that are in a direct line of site of the transmitting ultrasonic device **18**. As tissue density changes for regions in the direct line-of-flight between the transmitting sensor **18** and the receiving sensor **18**, the signal received by the receiving sensor **18** is altered relative to previously collected/stored data.

[0019] The sensor garment **12** fits firmly against the breasts of the patient such that all ultrasonic devices **18** are in solid contact with the breasts. In one embodiment, the devices **18** are fixed to the inside surface of the garment **12** such that one face of the sensor device **18** is in contact with the patient's skin. A firm fitting garment also assists the patient in wearing the garment in the same relative position for each examination such that the cancer detection system **10** reveals consistent results. Because a woman may not wear the sensor garment **12** in exactly the same position for each examination, the computer processing of the cancer detection system **10** references the patient's chronological profile and compensates for the misalignment.

[0020] A local processing device **20** in electrical communication with the ultrasonic devices **18** is employed for system control, data collection, user interface, and communication. In one embodiment, prior to each examination, a patient enters a password into the local processing device **20** to identify the patient and provide patient privacy and security. Upon each examination request, a breast examination program is loaded to the local processing device **20** by a remote processing device **22** after the remote processing device **22** confirms the user password. Once programmed, the local processing device **20** governs the breast examination, collects the readings from the ultrasonic devices **18**, performs noise reducing signal processing, and temporarily stores this information. Once the readings have been collected by the local processing device **20**, the remote processing device **22** retrieves the readings, performs signal analysis, and adds the results to the chronological profile of the patient. Signal processing is then performed on the profile in order to detect any developing localized tissue abnormalities. If alerted to a potential abnormality, the doctor of the patient then accesses the patient's profile from the remote processing device **22** and conducts his/her diagnosis.

[0021] In the illustrated embodiment, the local processing device **20** communicates with the remote processing device **22** by way of the Internet. In one embodiment, the Internet-based connection is achieved by connecting the local processing device **20** and the remote processing device **22** to respective general purpose computers capable of accessing the Internet. In another embodiment, the Internet-based connection is achieved by providing the local processing device **20** and the remote processing device **22** with a capability for accessing the Internet. However, those skilled in art will recognize that the utilization of an Internet-based connection is not required to remain within the scope or spirit of the present invention. For example, in one embodiment, the information obtained from the sensor garment **12** and the local processing device **20** is stored on a data storing medium and physically delivered to the patient's doctor. In another embodiment, the local processing device **20** is connected to the remote processing device **22**, such as through a network connection.

[0022] The remote processing device **22** uses signal analysis algorithms to examine the most recent data and compare that data to previously recorded data. If, during the analysis and comparisons, possible localized tissue changes are detected, then the remote processing device **22** generates an alert. The alert prods a physician to review the data and determine whether additional diagnostic procedures need to be pursued. The remote processing device **22**, in various embodiments, 1) communicates with the sensor garment **12** via the local processing device **20** to control data acquisition, data analysis, and data storage; 2) provides the test program for the sensor garment **12**; 3) collects and stores transmission data; 4) performs the analysis of current and previously collected data; 5) runs updated software routines against the collected data as the software evolves; and 6) communicates with the patient and physician to provide status of the data analysis and alerts if suspect tissue growth is detected.

[0023] In another embodiment, the patient puts on the sensor garment **12** and the local processing device **20** controls the data acquisition for a complete breast examination. The local processing device **20** stores the collected data for transferal to the remote processing device **22**, which stores the data and performs processing for diagnoses.

[0024] The sensor garment **12** provides the function of positioning the sensors **18** against the breast. The sensor garment **12**, in combination with the coupling agent **26** (discussed below), also functions to secure the sensors **18** against the breast. In one embodiment, the local processing device **20** provides the function of acquiring the data received by the sensors **18**. The remote processing device **22** provides the function of processing the data acquired by the local processing device **20**. In another embodiment, a single processing device performs the functions of acquiring data from the sensors **18** and processing the acquired data.

[0025] Figure 2 is a block diagram illustrating one embodiment of the electrical components of the cancer detection system **10**. In the illustrated embodiment, a controller device **32** governs the general operation of the local processing device **20**. The controller device **32** communicates with the patient

through a user interface **34** and upon the patient's request of a breast examination, the controller device **32** obtains the breast examination program from the Internet through an Internet device **36** and stores the program information in a general purpose memory **38**. After the breast examination program has been loaded, the corresponding pulse signal to be transmitted through the breast is stored in a pulse signal memory **40**.

[0026] An application specific integrated circuit (ASIC) controller **42** is employed to conduct the data acquisition. After being prompted by the controller device **32**, the ASIC controller **42** activates a pulse generator **44** that reads the specified pulse signal from the pulse signal memory **40**, converts the digital signal to an analog signal, and transmits the signal to a signal router **46**, which distributes the signal to a specific sensor **18**. The signal router **46** then directs the signal received by a specific sensor **18** to a signal amplifier **48**. The ASIC controller **42** provides the desired magnitude of signal amplification to a time vs. gain adjustment module **50**, which adjusts the signal amplifier **48** accordingly. The amplified signals are then read by an analog-to-digital converter **52**, which digitizes each signal. The digitized signals are stored in a tissue signal memory **54** until the controller device **32** requests the signals for noise reducing signal processing, which is performed by the controller device **32**. The controller device **32** then transmits the results through the Internet device **36**, across the Internet, and to the remote processing device **22**.

[0027] Those skilled in the art will recognize that electronic configurations for the local processing device **20** other than the previously discussed configuration may be used without interfering with the scope or spirit of the present invention. For example, in another embodiment, the controller device **32** includes programming for performing the tasks of the ASIC controller **42**. Due to the high-speed nature of the data collection process, this embodiment requires the controller device **32** to be a high-speed device.

[0028] Another embodiment of the local processing device **20** has an analog-to-digital converter (ADC) and a digital-to-analog converter (DAC) for each sensor **18**. A processor sends data to one sensor's DAC for that sensor to transmit, all the

other sensors receive the transmitted signal and the processor transfers the data acquired from each ADC to memory during the data acquisition phase. Each sensor **18** sequentially transmits a signal for a complete examination. Once all the data is acquired and stored in memory, the data can be processed either with the local processing device **20**, in one embodiment, or processed remotely by the remote processing device **22**, in another embodiment.

[0029] Figure 3 is a flow diagram illustrating the general operational behavior of the embodiment of the local processing device **20** illustrated in Figure 2. A breast examination begins at block **76** where a breast examination is requested by a patient by way of the user interface **34**. Once requested, a breast examination program is loaded by way of the Internet from the remote processing device **22**. Then, at block **78**, the sampling parameters of the ASIC controller **42** are set up by the controller device **32** for a background noise test. The background noise test is the acquisition of noise such as the patient's heartbeat, blood flow, ultrasonic sensor component noise, electronics noise, or external noise such as conversation. The background noise test is independently and sequentially performed for each sensor **18** in order to determine the characteristics of the background noise at the location of each sensor **18**. The background noise test allows the cancer detection system **10** to account for and eliminate signal degenerating noise during signal processing. The background noise test is performed at block **80**.

[0030] At block **82**, the sampling parameters of the ASIC controller **42** are set up by the controller device **32** for a distance test. The distance test determines the physical size of a breast at the time of examination and provides data used by the processing routines. More specifically, the distance test determines a signal's time-of-flight between any two sensor **18** with a direct line-of-flight in order to calculate the desired initiation and duration of received signal sampling. The time-of-flight for a signal between two sensors **18** is determined by beginning sampling at a receiving ultrasonic device at the moment a pulse is transmitted from a corresponding transmitting ultrasonic device. The number of samples collected before the pulse is detected by the receiving ultrasonic device is converted to a value of time by considering the current sampling rate. This value of time is the

time-of-flight for a signal of the corresponding sensor **18** combination. Additionally, once the physical size of a breast has been calculated, the maximum distance possible for a reflected signal to travel before reaching its receiving ultrasonic device is determined and converted to a corresponding maximum propagation time. Therefore, the time-of-flight and the maximum propagation time allow the local processing device **20** to establish an initiation and duration for the sampling of a received signal for each of the sensor **18** combinations.

[0031] It can be understood from previous discussion that the results of the distance test are used to calibrate the time vs. gain module **50** of Figure 2. The distance test is performed at block **84**. Finally, the sampling parameters of the ASIC controller **42** are set up by the controller device **32** for tissue data collection at block **86**. The tissue data collection, performed at block **88**, is illustrated and discussed in subsequent discussion.

[0032] In one embodiment, as a form of noise reducing signal processing, a packet of 1000 signals is transferred for each ultrasonic device **18** transmitter-receiver combination. The 1000 values received are then averaged to eliminate any random noise. The noise reducing signal processing is performed at block **90** by the controller device **32**. The averaged signal value is then stored in the general purpose memory **38** until the complete set of data from the tissue data collection is transferred to the remote processing device **22** at block **92**.

[0033] Figure 4 illustrates a perspective view of a sensor device **18** of Figure 1, and Figure 5 illustrates the ultrasonic device **18** in section, taken along lines 5-5. In one embodiment the sensor device **18** is an ultrasonic transducer. In another embodiment, the ultrasonic transducer is a polyvinylidend fluoride (PVDF) piezoelectric transducer. In still another embodiment, the ultrasonic transducer is a ceramic piezoelectric transducer.

[0034] The ultrasonic device **18** is a coin-shaped device, which, in one embodiment, is 0.25 inches in diameter and 0.25 inches in depth. Those skilled in the art will recognize that other shapes and dimensions for the ultrasonic device **18** may be used without interfering with the scope or spirit of the present invention. The sensor device **18** of the illustrated embodiment includes a housing

24 for mounting the sensor **18** within the sensor garment **12** and for accommodating a coupling agent **26**, a transceiver **28**, and a transceiver backing **30**. The coupling agent **26** provides connectivity between the transceiver **28** and the breast and eliminates an air boundary layer between the transceiver **28** and the breast. The coupling agent **26** is composed of a material that allows ultrasonic energy to pass through the coupling agent **26** in the same manner that ultrasonic energy passes through human tissue. The characteristics of the coupling agent **26** eliminate the necessity of the messy ultrasound gel required in prior art clinical examinations. The coupling agent **26** of the illustrated embodiment has a contour that is a truncated cone, defined by the housing **24** and the transceiver **28**, in order to guide ultrasonic energy transmitted and received by the transceiver **28**. The transceiver **28** of the illustrated embodiment is a piezoelectric transceiver that is capable of transmitting and receiving ultrasonic energy. Those skilled in the art will recognize that other devices may be used without interfering with the scope or spirit of the present invention.

[0035] The transceiver backing **30** and the housing **24** are constructed of a material that absorbs ultrasonic energy such that the signal emitted from the transceiver **28** is focused in the direction of the coupling agent **26** and the signal received by the sensor **18** is focused toward the transceiver **28**.

[0036] The ultrasonic signal transmitted by the sensor **18** is an ultrasonic pulse that propagates through a breast. With a point transmitting source, a signal radiates with an expanding spherical pattern. Considering the structure of the sensor **18** depicted in Figure 4, in the embodiment in which the sensor **18** is 0.25 inch in diameter, the transmitting surface **28** of the sensor **18** is slightly smaller than the 0.25 inch diameter of the complete device. The radiation pattern of the ultrasonic sensor **18** is spherical, but with a base diameter of slightly less than 0.25 inches.

[0037] Figure 6 is a flow diagram illustrating a single signal transmission and reception as performed by the ultrasonic devices **18**. A receiving ultrasonic device receives a signal having three signal components, namely a background signal component, a direct line-of-flight signal component, and a reflected signal

component. The background signal component is acquired by the receiving ultrasonic device **18** prior to the reception of a signal from a transmitting ultrasonic device at block **56**. The background signal component comprises the background noise detected by the receiving sensor **18**, such as the patient's heartbeat, blood flow, ultrasonic sensor component noise, electronics noise, and external noise such as conversation. The background signal component allows the cancer detection system **10** to account for and eliminate signal degenerating noise during signal processing.

[0038] At block **58**, the transmitting sensor **18** transmits a pulsed signal that propagates through breast tissue. Although only one signal is transmitted, the receiving sensor **18** receives the transmitted signal as the direct line-of-flight signal component and the reflected signal component. The direct line-of-flight signal component is the portion of the signal that has a direct line-of-flight from a transmitting sensor **18** to a receiving sensor **18**. The function of the direct line-of-flight signal component is to detect a localized tissue density change (normal or abnormal) through the analysis of the signal component's amplitude at a receiving sensor **18** and to provide the cancer detection system **10** with a location of the localized tissue density change. Because the direct line-of-flight signal component travels a lesser distance than the reflected signal component, the direct line-of-flight signal component will arrive at the receiving sensor **18** prior to the reflected signal component, as indicated at block **60**.

[0039] The reflected signal component is the portion of a signal that reaches the receiving sensor **18** after reflecting off of a localized tissue abnormality. The function of the reflected signal component is to detect and determine the size of a localized tissue abnormality through analysis of the time-of-flight of the signal component, as revealed in subsequent discussion. The reflected signal component is received by the receiving ultrasonic device **18** at block **62**.

[0040] Figure 7 is a sectional view of the sensor garment **12** illustrating the detection of a localized tissue abnormality by direct line-of-flight signal components. In the illustration, a transmitting ultrasonic device **64** emits a signal that propagates through the breast tissue; however, Figure 7 depicts only the

direct line-of-flight signal components for a few receiving sensors **68**, **72**, **76**, **80**. More specifically, a first direct line-of-flight signal component **66** is received by a first receiving ultrasonic device **68**, a second direct line-of-flight signal component **70** is received by a second receiving ultrasonic device **72**, a third direct line-of-flight signal component **74** is received by a third receiving ultrasonic device **76**, and a fourth direct line-of-flight signal component **78** is received by a fourth receiving ultrasonic device **80**. In one embodiment, a single signal is transmitted and the receiving sensors **68**, **72**, **76**, **80** simultaneously monitor for received signals. In another embodiment, the sensors **68**, **72**, **76**, **80** sequentially monitor for a series of signals transmitted by the transmitted sensor **64**.

[0041] The first direct line-of-flight signal component **66** and the fourth direct line-of-flight signal component **78** reach their respective receiving ultrasonic devices without encountering a localized tissue abnormality. However, the second direct line-of-flight signal component **70** and the third direct line-of-flight signal component **74** encounter a localized tissue abnormality **82**, which is a region, or volume, of tissue having different density than the surrounding region, before reaching their respective receiving ultrasonic devices. The effect of a localized tissue abnormality **82** is to reduce the amplitude of the signal received by sensors **72** and **76**.

[0042] Figure 8 is a timing diagram that illustrates the direct line-of-flight signal components depicted in Figure 7. Figure 8 illustrates the embodiment in which a single pulse is transmitted and the receivers simultaneously monitor. The top diagram shows the transmitted signal emitted by transmitting ultrasonic device **64**. The diagrams below illustrate the corresponding signal components received by the receiving ultrasonic devices **68**, **72**, **76**, **80**.

[0043] Figure 8 illustrates a first time delay **84** that was previously calculated by the distance test as the time-of-flight for a signal traveling between the transmitting ultrasonic device **64** and the first receiving ultrasonic device **68**. This time delay **84** corresponds to the distance between the transmitting sensor **64** and the receiving sensor **68**. The speed of sound in fat tissue has been determined to be 0.145 centimeters per microsecond. By multiplying the time **84** in

microseconds by this factor, the number of centimeters between the sensors **64** and **68** is determined. In one embodiment, the first receiving ultrasonic device **68** does not begin sampling the first direct line-of-flight signal component **66** until after the calculated time delay **84**. Also, as calculated during the distance test, the first receiving ultrasonic device **68** does not discontinue sampling the first direct line-of-flight signal component **66** until after the expiration of the maximum propagation time. In the same manner, a second time delay **94**, a third time delay **96**, and a fourth time delay **98** dictate the distance between the sensors and the sampling initiation of the second receiving ultrasonic device **72**, the third receiving ultrasonic device **76**, and the fourth receiving ultrasonic device **80**, respectively. The duration of sampling for each receiving ultrasonic device is controlled by its corresponding maximum propagation time.

[0044] Ultrasonic signals are attenuated by fat tissue. The amount of attenuation is determined by the distance that the signal travels through fat. For any non-fat tissue that the signal passes through, for example, a localized tissue abnormality, the attenuation will vary. A normalized amplitude can be determined by calculating the expected amplitude of the signal for the distance that the signal travels through fat tissue, which is known, as described above. An amplitude less than this normalized value indicates an area of denser tissue in the signal path.

[0045] The first direct line-of-flight signal component **66** does not encounter a localized tissue abnormality, and it has a normalized amplitude value of 1 at the time it is received. The same is true for the fourth direct line-of-flight signal component **78**. However, the second and third direct line-of-flight signal components **70** and **74** do encounter a localized tissue abnormality, and they have a normalized amplitude value of less than 1 at the time they are received. These levels are indicated on Figure 8. From this information, it can be concluded that there is an obstruction in the signal paths **70** and **74** that possibly indicate a localized tissue abnormality **82**. In one embodiment, a threshold value can be applied to the normalized value to indicate that the abnormality **82** is of such a size or density that it obstructs the signal a specified amount. In another embodiment, the normalized amplitude is used to determine the size of the abnormality **82**. That is, larger abnormalities attenuate more.

[0046] Figures 7a and 7b illustrate the signal path between the transmitting sensor **64** and the receiving sensor **72** for two sizes of localized tissue abnormalities **82'** and **82"**. The sensors **18** have a circular transducer, which in one embodiment is less than 0.25 inches. Accordingly, a transmitter and a receiver directly opposite each other have a signal path that is cylindrical in shape and extends between the transmitter and receiver. For receivers that are not directly opposite the transmitter, the signal path becomes an oblique cylinder, with the cylinder becoming more oblique as the receiving sensor deviates further from the perpendicular of the transmitting sensor.

[0047] Figure 7a illustrates a localized tissue abnormality **82'** that is large, but does not fall totally within the signal path **70'**. Figure 7b illustrates a localized tissue abnormality **82"** that is smaller, but does fall within the signal path **70"**. In each of these instances, the amplitude of the signal received by the sensor **72** will be reduced. The received signal **70'** and **70"** does not indicate where along the signal path the abnormalities **82'** and **82"** are located.

[0048] Figure 9 is a sectional view of the sensor garment **12** illustrating the reflected signal components for the transmitted signal illustrated in Figure 7. A first reflected signal component **86** is reflected by the localized tissue abnormality **82** and is received by the first receiving ultrasonic device **68**. Because the first reflected signal component **86** travels a greater distance and is reflected by the localized tissue abnormality **86**, the first reflected signal component **86** is received after the first direct line-of-flight signal component **66** and has a lesser amplitude value. Figure 8 illustrates the time-of-flight **100** for the received signal **86**. This time-of-flight **100** determines the distance that the signal **86** traveled. The distance traveled by a reflected signal component is the sum of the distance traveled prior to encountering a localized tissue abnormality **82** and the distance traveled after encountering the localized tissue abnormality **82**. At the point where a reflected signal component encounters a localized tissue abnormality, the propagation path of the signal is altered. A geometric surface is calculated such that any possible location of a propagation path alteration associated with a given total distance traveled by a reflected signal component **86** is located on the geometric surface. Therefore, knowledge of the distance covered by a reflected

signal component **86** allows the location of a surface of the localized tissue abnormality **82** to be determined within a geometrically calculated three-dimensional surface **92** that has a longitudinal axis corresponding to the direct line-of-flight signal component. The degree of location provided by the reflected signal components complements, confirms, and refines the locations provided by the direct line-of-flight signal components, as subsequently illustrated.

[0049] Similarly, the characteristics of a fourth reflected signal component **88**, received by the fourth receiving ultrasonic device **80**, are illustrated in Figure 8 and Figure 9. The characteristics of the received signal, including a second reflected signal component time-of-flight **102**, are analyzed in the way the characteristics of the first reflected signal component **86** are analyzed. Therefore, a corresponding geometrically calculated three-dimensional surface **104** is utilized to determine the location of a surface of the localized tissue abnormality **82** as somewhere along the geometrically calculated surface. It can be seen from Figure 9 that the plurality of geometrically calculated surfaces produced by several reflected signal components reduce the possible locations of a localized tissue abnormality. Additionally, the plurality of geometrically calculated surfaces provides information relating to the size of the detected localized tissue abnormality **82**.

[0050] Figure 10 is a sectional view of the sensor garment **12** further illustrating the detection of a localized tissue abnormality **82** by direct line-of-flight signal components **96**. Considering the detection techniques discussed with Figure 7, a present localized tissue abnormality **82** is detected by a direct line-of-flight signal component and considered positioned between the two corresponding sensors **18**. Therefore, a plurality of direct line-of-flight signal components, encountering a localized tissue abnormality **82** from varying perspectives, is able to reveal a specific location of the tissue abnormality. Thus, in the illustrated embodiment, the intersections of detecting direct line-of-flight signal components **96** reveal the location of the localized tissue abnormality **82**. Those skilled in the art will recognize that although Figure 9 illustrates a two dimensional plane of signal components, the sensor garment **12** provides three dimensional coverage of

a breast, thus allowing the sensors **18** to produce a location of a localized tissue abnormality anywhere in the breast.

[0051] Figure 11 is a sectional view of the sensor garment **12** illustrating the planar signal coverage provided by multiple transmitting and receiving sensors **18**. Figures 7, 7a, 7b, 9, 10, and 11 illustrate a section of the garment **12** and the illustrated sensors are all located in one plane. Each cup **14**, **16** of the garment **12** has numerous sensors **18** located adjacent each other, providing three-dimensional coverage of the breast. For x number of sensors **18**, there are theoretically x * (x – 1) signal paths available. That is, for a garment cup **14**, **16** with 30 sensors, 870 direct signal paths would be generated if each sensor **18** transmitting a signal is received by every other sensor **18**. In practice, the number of direct signal paths is less because the sensors **18** adjacent the transmitting sensor **18**, which would lie in almost the same plane as the transmitting sensor **18,** would not be able to receive a useful signal. This condition is illustrated in Figure 11. In the illustration, only the direct line-of-flight signal components are depicted in order to maintain intelligibility of the figure. The intersecting signals indicate that any localized tissue abnormality will be encountered numerous times from numerous perspectives.

[0052] By considering the reflected signals, the number of signals received is increased over the number of direct signals received. These additional signals are useful for refining the location of any localized tissue abnormality. Additionally, the patient's rib cage and associated musculature will produce a wall of reflected signals indicating the extent of the breast examination. Any abnormalities located adjacent the rib cage would be indicated by reflected signals.

[0053] After the signal data is collected and stored for each breast, the raw data is further processed to produce a virtual breast, which is a map of tissue density within a patient's breast. With periodic examinations, a chronological profile of virtual breasts is constructed for a patient. The virtual breasts are compared with regard to time and any long-term changes within the breast tissue are detected. These long-term changes are typically indicators of cancerous tumors. In one embodiment, the raw data is processed using Fourier transforms to

reduce the data such that a doctor can perform meaningful diagnoses and analysis.

[0054] The remote processing device **22** stores the data collected from each breast examination. The data from each breast examination is added to a chronological profile of the patient's breast tissue development. The chronological profile contains a record of breast examinations over a period of examinations. The chronological profile provides an indication, over time, of tissue density changes in the patient's breasts. These changes may be due to normal changes of the breast tissue, or they may be due to a cancerous growth. The data in the chronological profile is available, in one embodiment, for re-analysis with updated or different software to determine and/or identify changes in the breast tissue over time.

[0055] The number of sensors **18** and the size of the transceiver **28** determine the resolution and precision of the cancer detection system **10**. In one embodiment, the sensors **18** are positioned within the sensor garment **12** such that they produce a resolution capable of detecting a localized tissue abnormality with a diameter of only a few millimeters.

[0056] The features of the present reveal a self-contained cancer detection system capable of reliably detecting an existing localized tissue abnormality in its primary stages of development. Because of the structure and operational behavior of the elements of the cancer detection system **10**, a trained ultrasonographer is not required to operate the device. Therefore, the cancer detection system **10** is used and operated by the patient herself in the privacy and convenience of her own home. The privacy and convenience associated with the use of the cancer detection system **10** promote more frequent breast examinations for more women. This, in turn, leads to more early detections of breast cancer, which lead to more successful treatments for this fatal disease.

[0057] From the foregoing description, those skilled in the art will recognize that a system for detecting breast tumors offering advantages over the prior art has been provided. The system provides an at-home breast examination that ultrasonically maps the breast tissue of a patient without the requirement of a trained ultrasonographer and relays the results of the examination to the remote

processing device by way of the Internet or other transmission media. Additionally, the system builds a chronological profile of the patient's breast tissue structure that can be analyzed automatically or by a physician to monitor abnormal developments in the breast tissue. Finally, the system accounts for user error such as not wearing the garment in the same position for each examination by referencing the discussed chronological profile.

[0058] While the present invention has been illustrated by description of several embodiments and while the illustrative embodiments have been described in considerable detail, it is not the intention of the applicant to restrict or in any way limit the scope of the appended claims to such detail. Additional advantages and modifications will readily appear to those skilled in the art. The invention in its broader aspects is therefore not limited to the specific details, representative apparatus and methods, and illustrative examples shown and described. Accordingly, departures may be made from such details without departing from the spirit or scope of applicant's general inventive concept.